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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,653	01/22/2005	Oleg Iliich Epshtein		8593

7590 07/09/2007

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EXAMINER	
SZPERKA, MICHAEL EDWARD	
ART UNIT	**PAPER NUMBER**
1644	
MAIL DATE	**DELIVERY MODE**
07/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,653	EPSHTEIN ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) *4 and 5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response received April 19, 2007 is acknowledged.

Applicant's election of Group I, claims 1-3, drawn to compositions comprising antibodies that bind prostate-specific antigen in the reply filed on April 19, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 4 and 5 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 19, 2007 as explained above.

Claims 1-3 are under examination in the instant office action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The term "ultra-low" in independent claim 1 is a relative term that renders the claims indefinite. The instant specification does not provide a definition for "ultra-low".

The dosage range encompassed by the recitation of "ultra-low" is so vague that the metes and bounds of the claims cannot be determined.

B) Independent claim 1 is indefinite in the recitation of "exposure to external factors preferably in accordance with homeopathic technology". The instant specification does not define the term "external factors", and thus the metes and bounds of the claims cannot be established. The specification exemplifies "external treatments" as being exposure to ultrasonic, electromagnetic, or other physical factors on page 2, but what are these factors? Heat is a physical factor, and so are the claims intended to encompass heating of the antibodies, a process that presumably would result in denaturation and thus loss of antibody activity?

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-3 rejected under 35 U.S.C. 103(a) as being unpatentable over Sinha (US patent 6,379,669, of record) in view of Davenas et al., Epshtein et al., and Feldman et al. (US Patent 5,741,488).

Sinha teaches antibodies to prostate-specific antigen (PSA) and their methods of production (see entire document, particularly the abstract and columns 7 and 8). These

antibodies are taught as being present in compositions for use in methods of treatment (see particularly column 9).

These teachings differ from the instant claimed invention in that the antibodies in the compositions of Sinha are not disclosed as having been made by multiple consecutive dilutions and exposure to external factors.

Davenas et al. teach very low concentrations (i.e. ultra low) of anti-IgE antibodies produced by repeated serial dilutions and exposure to the external factor of mixing by using a vortex (see entire document, particularly page 816 and the legend of Fig. 1). These antibodies maintain their ability to induce a physiological response, measured by the basophil degranulation, even at such low concentrations (see particularly the abstract, figure 1, and Tables 1-3).

Epshtein et al. teach that potentiated antiserum when administered in very low doses causes measurable biological responses in vivo (see entire document, particularly the abstract).

Feldman et al. teach that antibody based therapies are expensive and that lower doses of antibodies offer the advantage of lower financial costs to the patient (see entire document, particularly lines 20-25 of column 3).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to make compositions comprising very low doses of anti-PSA antibodies. Motivation to do so comes from the teachings of Sinha that his anti-PSA antibodies are to be used for methods of treatment, the teachings of Feldman et al. that low doses of antibody result in lower financial costs to patients, and the teachings of Davenas et al. and Epshtein et al. that very low doses of antibody maintain biological activity. As such, the skilled artisan would be able to make a biologically effective medicament that would impose less financial costs on patients. A person of ordinary skill in the art would have a reasonable expectation of success in making and using such compositions based upon the two distinct model systems of Davenas et al. and Epshtein et al., both of which disclose that antibody solutions maintain biological activity even when highly diluted.

Further, the courts have held that where the general conditions of a claim are

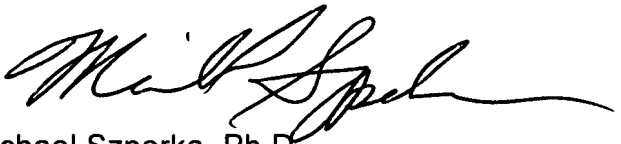
disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). See MPEP § 2144.05. Note that in the instant situation, the general conditions are disclosed by Salerno and identifying optimum or workable ranges for dilutions of the antibodies disclosed by Salerno requires only routine skill in the art.

5. No claims are allowable.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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June 26, 2007